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EXAMINER
PICCONE, L

ART UNIT 152 | PAPER NUMBER 11

DATE MAILED: 01/25/91

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-18 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-18 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

15.

Claims 1-4, 11, 12, 15 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

claim 1 use improper Markush language. Claim 1 should read....a member selected from the group.... Claims 2-4 refer to %'s of azelastine but do not indicate the applicability to the physcologically acceptable salts. Claim 12 has the same language as claim 1. The phrase "predetermined amount in claim 15 is indefinite. Claim 18 is improper and indefinite. What are conventional pharmaceutical carrier substances?

16.

Claims 11 and 18 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to those that are in the form of solutions, suspensions, oilments, creams, gels and dosage aerosols as disclosed on page 5 lines 15-16 of the specification. See M.P.E.P. §§ 706.03(n) and 706.03(z).

17.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the

date of application for patent in the United States.

18.

Claims 1, 6, 7, 9, 10, 11 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vogelsang U.S> Patent 3,813,384.

Vogetsang teaches the use of substituted benzyl phthalazone derivities (column 1 line 16) as antihistamines (column 1 line 35). Azelastine is a species of the generic substituted benzyl phthalazone at column 1 line 60 when R_1 = chloro, R_2 = H P=O and y is a 7 member ring with an amine group with a methyl group as one of its substituted groups. Azelastin is the compound of Example 38 (column 10 line 30).

Vogelsang discloses the use of azelastine in a pharmaceutical preparation that can be administered in usual embodiments such as tablets, dragers, drops ointments and creams. (Column 6 line 66). Column 6 line 21 disclose the aerosol use of a substituted benzyl phthalazone derivative. Thus claims 1, 6, 7, 9, 10, 11 and 12 are met.

19.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

20.

Claims 2, 3, 4 rejected under 35 U.S.C. § 103 as being unpatentable over Vogelsang teaches Azelastine in a composition for direct administration to the nose of eye (column 1 line 57, column 6 line 65) thus meeting claims 1 and 12. Vogelsang teaches at column 7 line 2 that the recommended dosage of substituted benzyl phthalazone derivative is .4 to 4 mg per day for human patients. Claims 2, 3 and 4 would have been obvious because the proportion or amount of each ingredient is a result effective parameter dependant upon the desired medicinal effect. It would have been obvious to adjust the amount of each ingredient to optimize the effect. In the absence of new and unexpected results which differ in kind and nature it would have been obvious to vary the amount or proportion of each ingredient. The declarations submitted on February 12, 1990 and June 18, 19990 are unconvincing as to new and unexpected results in that they do not agree with the scope of the claims. All of the claims in the subject application fall within a range of from